AUG 8 - 2005

SENTINEL
DIAGNOSTICS

510k Summary
Sentinel C-Reactive Protein (CRP) Diagnostic Assay

K Number: K050836

1. Submitter's information:

Mr. Ugo De Luca
Managing Director
Sentinel CH Srl
Via Principe Eugenio
20155 Milan, Italy

Tel.: +39 02 345514 1
Fax: +39 02 345514 64
e-mail: sentinel@sentinel.it

2. Contact person:

Maria E. Donawa, M.D.
Donawa Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

Tel.: +39 06 578 2665
Fax: +39 06 574 3786
e-mail: medonawa@donawa.com

3. Date summary prepared: 31 March 2005

4. Device name and classification

The CRP Diagnostic Assay described in this 510(k) consists of reagents, calibrators and a control, packaged and distributed in five kits, but together making up the CRP assay. The device is intended to be sold as an *in-vitro* test for professional use.

Product name and classification information are provided in **Table 4.1** below.

Table 4.1 Device names and classification of Sentinel CRP DIAGNOSTIC ASSAY components

Common or usual name	Trade or Proprietary Name	Classification name	Class	Product Code	Classification panel
CRP diagnostic assay	CRP Vario	C-reactive protein immunological test system	II under 21 CFR 866.5270	DKC	Immunology
CRP calibrator	CRP Calibrator Set	Calibrator Primary	II under 21 CFR 862.1150	JIS	Immunology
CRP calibrator	CRP Calibrator US	Calibrator Primary	II under 21 CFR 862.1151	JIS	Immunology
CRP calibrator	CRP Calibrator WR	Calibrator Primary	II under 21 CFR 862.1152	JIS	Immunology
CRP control	CRP Control US	Quality Control Material (assayed and unassayed)	I, reserved, under 21 CFR 862.1660	JJY	Clinical Chemistry

SENTINEL DIAGNOSTICS SENTINEL CH. - Via Principe Eugenio, 5 - 20155 Milan - Italy
Ph. +39 02 3455141 - Fax +39 02 34551464 - www.sentinel.it - sentinel@sentinel.it

5. Device description

The Sentinel **CRP Vario** kit is a latex in vitro diagnostic immunoassay for the quantitative determination of C-reactive protein (CRP) in human serum and in heparinized and EDTA-plasma. Human CRP antigens in the sample bind to the specific anti-CRP antibody absorbed to latex particles, and agglutination occurs. This agglutination is detected as an absorbance change when read on an automated chemistry analyzer at wavelengths between 550 - 580 nm. The magnitude of the change in absorbance is proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration using the CRP Calibrator Set, CRP Calibrator US, or CRP Calibrator WR.

The Sentinel **CRP Calibrator Set**, **CRP Calibrator US** and **CRP Calibrator WR** are prepared by diluting purified CRP with normal human serum to reach CRP concentrations of 0.25, 0.5, 1.0, 2.0, 4.0, 8.0, 16.0, 32.0 and 48.0 mg/dL.

By using the CRP Vario with the Sentinel calibrator kits, each used with specific analyzer settings called Methods, three measuring ranges can be achieved. The combinations of calibrators, method used and analytical ranges are listed in **Table 5.1**.

Table 5.1 Method, calibrators, and analytical ranges for CRP Vario

Application Method	Calibrators	Analytical Range
Standard Method	CRP Calibrator Set	0.02 – 32.0 mg/dL
Ultrasensitive Method	CRP Calibrator Set and CRP Calibrator US	0.01 – 16.0 mg/dL
Wide Range Method	CRP Calibrator Set and CRP Calibrator WR	0.02 – 48.0 mg/dL

The Standard and the Wide Range Methods can be used with any available commercial quality control materials. The CRP Vario with the Ultrasensitive Method requires a Sentinel control, **CRP Control US,** for the approximate CRP concentration of 0.05 mg/dL to ensure the effectiveness of CRP measurements at very low CRP concentrations.

6. Intended Use

CRP Vario is an in vitro diagnostic test for the quantitative determination of C-reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury and inflammatory disorders.

CRP Calibrators (CRP Calibrator Set, CRP Calibrator US and CRP Calibrator WR) are intended to be used for the calibration of the CRP Vario for the quantitative determination of C-reactive protein in human serum and EDTA or lithium heparinized plasma samples.

CRP Control US is intended for use as an assayed quality control material for serum C-reactive protein analysis.

SENTINEL DIAGNOSTICS SENTINEL CH. - Via Principe Eugenio, 5 - 20155 Milan - Italy
Ph. +39 02 3455141 - Fax +39 02 34551464 - www.sentinel.it - sentinel@sentinel.it

7. Comparison with Predicate Devices

Table 7.1 below provides a list of predicate devices for the Sentinel CRP Diagnostic Assay devices.

Table 7.1 Predicate devices for Sentinel CRP DIAGNOSTIC ASSAY devices

#	Sentinel Device Trade Name	Predicate Device Name	Predicate Device Manufacturer	Predicate device (S) n.	FDA clearance date
6	CRP Vario	CRP-Latex (II)X2 SEIKEN	Denka Seiken Co.	k030545	6 Feb. 2003
7	CRP Calibrator Set	CRP(II) Calibrators	Denka Seiken Co.	k030546	6 Feb. 2003
8	CRP Calibrator US used with CRP Calibrator Set	CRP(II) Calibrators	Denka Seiken Co.	k030546	6 Feb. 2003
9	CRP Calibrator WR used with CRP Calibrator Set	Immage Immunochemistry System CRP reagent	Beckman Coulter, Inc.	k981638	6 Dec. 1998
10	CRP Control US	hsCRP Control Level 1	CLINIQA	k011169	18 May 2001

The Sentinel's CRP reagents, calibrators and control and the predicate devices are both used for the determination of C-Reactive protein. In addition, they use the same::

- Sample type: human serum and plasma
- Technology: latex particle agglutination
- Antibody: rabbit polyclonal
- Detection method: agglutination measurement
- Calibration: against multipoint calibrators.

However, CRP Vario must be used with the Abbott AEROSET® and ARCHITECT® analyzers, whereas the Denka Seiken CRP-Latex (II)X2 Assay Kit labeling indicates that the product can be used with any automated clinical chemistry analyzer.

8. Performance Data

Performance evaluations included sensitivity, intra- and inter-assay precision, prozone and interference testing. In addition, Sentinel performed comparisons between the Sentinel CRP assay and the Beckman Coulter IMMAGE Immunochemistry System CRP reagent. Equivalence was demonstrated across the total measurement range of0.01 to 48.0 mg/dL.

9. Conclusion

The performance and safety data presented in this premarket notification support a finding of substantial equivalence between the Sentinel CRP Diagnostic Assay and the predicate devices specified in this submission.

SENTINEL DIAGNOSTICS
SENTINEL CH. - Via Principe Eugenio, 5 - 20155 Milan - Italy
Ph. +39 02 3455141 - Fax +39 02 34551464 - www.sentinel.it - sentinel@sentinel.it

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2005

Sentinel CH Srl
c/o Maria E. Donawa, M.D.
Donawa Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

Re: k050836
Trade/Device Name: CRP Calibrators (including CRP Calbrator Set, CRP Calibrator US and CRP Calibrator WR)
CRP Vario
CRP Control US
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK, JIS, JJY
Dated: June 23, 2005
Received: July 6, 2005

Dear Dr. Donawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050836

Device Name: CRP Calibrators (including CRP Calibrator Set, CRP Calibrator US and CRP Calibrator WR)

Indications for Use:

CRP Calibrators (CRP Calibrator Set, CRP Calibrator US and CRP Calibrator WR) are intended to be used for the calibration of the CRP Vario for the quantitative determination of C-reactive protein in human serum and EDTA or lithium heparinized plasma samples.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050836

Indications for Use

510(k) Number: K050836

Device Name: CRP Vario

Indications for Use:

CRP Vario is an in vitro diagnostic test for the quantitative determination of C-reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury and inflammatory disorders.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050836

Indications for Use

510(k) Number: K050836

Device Name: CRP Control US

Indications for Use:

CRP Control US is intended for use as an assayed quality control material for serum C-reactive protein analysis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050836